

REMARKS

Claims 104 and 107-112 are currently under examination in the Application. Reconsideration is respectfully requested in view of the following remarks.

Applicants wish to thank the examiner for noting that claims 104 and 107 are allowed.

***Rejections – 35 U.S.C. § 112, first paragraph (new matter)***

Claims 108-112 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the Applicants, at the time the application was filed, had possession of the claimed invention. In particular, the Action contends that there is no support for the term “composition” in claims 108-112 in that the specification only describes non-specific immune response enhancers in the context of the term “vaccine”. Accordingly, the Action concludes that claims 108-112 constitute new matter.

Applicants respectfully traverse this rejection on the following grounds. The Action contends that the art recognizes that the terms “composition” and “vaccine” differ in scope in that the art recognizes that a vaccine is used for treatment of disease including human disease, while the term “composition” does not necessarily imply that the composition would be used to treat human disease. Applicants submit that this assertion does not necessarily mean that Applicants were not in possession of compositions comprising an immunogenic portion of native WT1, wherein the immunogenic portion consists of the contiguous amino acids of SEQ ID NO:2, in combination with a non-specific immune response enhancer. In particular, Applicants submit that the specification as filed clearly contemplates using WT1 polypeptides in methods for stimulating and expanding WT1-specific T cells, both *in vitro* and *in vivo*. For example, Applicants direct the Office’s attention to the specification at page 4, lines 26-29 where the specification states:

In other aspects, the present invention provides methods for stimulating (or priming) and/or expanding T cells, comprising contacting T cells with a WT1 polypeptide under conditions and for a time sufficient to permit the stimulation and/or expansion of

T cells. Such T cells may be autologous, allogeneic, syngeneic or unrelated WT1-specific T cells, and may be stimulated *in vitro* or *in vivo*. (emphasis added)

Applicants submit that the skilled artisan would readily understand that “conditions sufficient to permit the stimulation and/or expansion of T cells” may include non-specific immune response enhancers, such as cytokines (e.g., IL-2), as described at page 26, lines 16-21 of the specification:

For therapeutic purposes, CD4<sup>+</sup> or CD8<sup>+</sup> T cells that proliferate in response to the WT1 polypeptide, polynucleotide or APC can be expanded in number either *in vitro* or *in vivo*. Proliferation of such T cells *in vitro* may be accomplished in a variety of ways. For example, the T cells can be re-exposed to WT1 polypeptide, with or without the addition of T cell growth factors, such as interleukin-2, and/or stimulator cells that synthesize a WT1 polypeptide.

As would be recognized by the skilled artisan, particularly in view of the teachings of the specification, for example, at page 30, line 28-page 31, line 6, non-specific immune response enhancers include cytokines. Accordingly, Applicants submit that the skilled artisan would readily appreciate that Applicants were in possession of compositions comprising WT1 polypeptides in combination with non-specific immune response enhancers.

Moreover, as outlined in Applicants’ response filed January 16, 2004, the specification as filed clearly describes compositions comprising WT1, for example, on page 9, line 25-page 10, line 2, as follows:

**The compositions described herein may include WT1 polypeptides, WT1 polynucleotides, antigen-presenting cells (APC, e.g., dendritic cells) that express a WT1 polypeptide, agents such as antibodies that bind to a WT1 polypeptide and/or immune system cells (e.g., T cells) specific for WT1.** (emphasis added)

The specification goes on to describe certain preferred embodiments of compositions, *e.g.*, vaccines, in the context of the present invention on page 28, lines 10 - 18 as follows:

**Within certain aspects, polypeptides, polynucleotides, antibodies and/or T cells may be incorporated into pharmaceutical compositions or vaccines.** Alternatively, a pharmaceutical composition may comprise an antigen-presenting cell (*e.g.*, a dendritic cell) transfected with a WT1 polynucleotide such that the antigen presenting cell expresses a WT1 polypeptide. Pharmaceutical compositions comprise one or more such compounds or cells and a physiologically acceptable carrier or excipient. **Certain vaccines may comprise one or more such compounds or cells and a non-specific immune response enhancer**, such as an adjuvant or a liposome (into which the compound is incorporated). (emphasis added)

Applicants submit that the skilled artisan would readily appreciate in light of this description that pharmaceutical compositions and vaccines are merely illustrative compositions comprising WT1 of the present invention. Applicants submit that the specification reasonably conveys to the skilled artisan that Applicants were in possession of the claimed compositions comprising a WT1 polypeptide and a non-specific immune response enhancer. Accordingly, Applicants respectfully submit that the instantly claimed subject matter does not constitute new matter and respectfully request that the rejection be withdrawn.

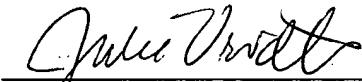
Application No. 09/164,223  
Reply to Office Action dated March 30, 2004

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all the claims remaining in the application are now believed allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

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